Proposed Proprietary Laboratory Analyses Panel Meeting Agenda - May 2022 Meeting

The proposed agenda for the May 2022 CPT® Proprietary Laboratory Analyses Panel meeting identifies the test names and requested descriptions for each test. The laboratory test name and test description detailed in this document are extracted from Applications submitted for discussion at this meeting. **Until such time as the Technical Advisory Group acts on these requests, the information that appears in this Proposed Agenda is provided for informational purposes only.**

Upon review of this agenda, if the reviewer believes that they will need to provide comment on an issue, they should send a request for a copy of the application and associated materials to Michael Pellegrino. This request for review of the application materials should contain the identity of the interested party seeking such and a brief summary of the basis for the request (e.g., associated vendor/ industry representative).

Any interested parties wishing to provide written comments on any agenda items should be aware of the relevant deadlines for reviewing and providing written comments to allow review by all parties (eg, Panel members, Technical Advisory Group reviewers, applicants, etc.). The applicant(s) who submitted the original code change application is automatically considered an interested party and is notified by AMA staff of any request for review submitted by another party. Interested parties should be advised of the expedited deadlines of the PLA code development process to facilitate quarterly submission, review and publication of Proprietary Laboratory Analyses Applications, in accordance with the timeframes defined in the Proprietary Laboratory Analyses (PLA) Calendar.

*Interested party requests will not be processed until the interested party submits a signed confidentiality agreement and disclosure of interest form. Interested party requests will be processed within 5 days of receipt of the requested forms. Written comments for these requests are due within 3 days upon receipt of materials, unless extenuating circumstances preclude the ability for interested parties to provide written comments for consideration within the defined timeframes.

During the time between now and the date of the meeting, the agenda will, most likely, be modified to reflect changes – additions, deletions or updates.

ID	Laboratory Test Name	Proposed Test Description
100836	EpiSwitch® Checkpoint-inhibitor Response Test (CiRT)	Oncology, DNA, 3D Genetic Profiling; eight (8) DNA regulatory (epigenetic) markers called chromosome conformation signatures (CCS) are extracted from whole blood and measured by quantitative PCR (qPCR), an algorithm stratifies patients based on their likelihood of responding to an Immune Checkpoint Inhibitor (ICI) therapy into either High or Low Probability of Response
100855	AllerGenis Peanut Diagnostic and Reactivity Threshold Assay	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of peanut allergy status, includes report of reactivity threshold level when performed
100885	HelioLiver	Surveillance for hepatocellular carcinoma (liver cancer) by next-generation sequencing of 77 CpG sites (28 genes) using cfDNA from plasma, and immunoanalyzer to determine the concentrations of 3 serum proteins alpha-fetoprotein (AFP), AFP-L3% and Des-gamma-carboxyprothrombin (DCP), algorithm reported as a qualitative result
100942	Guardant360 TissueNext	Targeted genomic sequence analysis panel, solid organ neoplasm, utilizing formalin-fixed paraffin embedded tumor tissue to analyze 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
101000	IriSight™ Prenatal Analysis – Proband	Reproductive medicine (Fetal constitutional heritable disorders), whole genome and mitochondrial DNA sequence analysis, including sequence analysis (single nucleotide variants, deletions/insertions, characterized intronic variants); copy number variants, duplications/deletions, mobile element insertions, uniparental disomy (UPD), inversions, and aneuploidy; mitochondrial genome sequence analysis with heteroplasmy and large deletions; and short tandem repeat expansion analysis in select genes. Amniotic fluid, cultured cells, or gDNA, identification and categorization of genetic variants, diagnostic report, fetus
101020	CellSearch® Circulating Multiple Myeloma Cell (CMMC) Test	Oncology (multiple myeloma, plasma cell malignancies and precursor diseases), circulating plasma cell immunologic selection, identification, morphological characterization, detection and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood
101022	IriSight™ Prenatal Analysis – Comparator	Reproductive medicine (Fetal constitutional heritable disorders), whole genome and mitochondrial DNA sequence analysis, including sequence analysis (single nucleotide variants, deletions/insertions, characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions, uniparental disomy (UPD), inversions, and aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, and short tandem repeat expansion analysis in select genes, Blood, identification and categorization of genetic variants, each comparator (parent)
101024	CellSearch® HER2 Circulating Tumor Cell	Oncology (breast, colorectal, esophageal, gastric, head and neck, and other HER2-

	(CTC-HER2) Test	overexpressing cancers of epithelial origin), circulating tumor cell immunologic selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18 and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker expressing cells, peripheral blood
101026	SelectMDx for Prostate Cancer	Oncology (prostate), mRNA expression profiling by real-time PCR of 2 genes (*HOXC6* and *DLX1*) utilizing first-void urine collected after digital rectal exam, algorithm reported as likelihood of high-grade cancer detection upon prostate biopsy
101027	Signatera MRD	Personalized, tumor-informed circulating tumor DNA (ctDNA) assay using bespoke mulitplex PCR and NGS to detect and quantify molecular residual disease (MRD) in patients with cancer. Cell-free DNA (cfDNA) found in plasma is isolated, amplified, sequenced, and analyzed to determine the presence/absence and quantity of ctDNA, which is correlated with the disease burden
101030	MatePair Acute Myeloid Leukemia Panel, Mayo Clinic, Laboratory Developed Test **DELETE 0056U**	~~0056U Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)~~
101031	MatePair Targeted Rearrangements, Congenital, Mayo Clinic **DELETE 0012U**	~~0012U Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)~~
101032	MatePair Targeted Rearrangements, Oncology, Mayo Clinic **DELETE 0013U**	~~0013U Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)~~
101033	MatePair Targeted Rearrangements, Hematologic, Mayo Clinic **DELETE 0014U**	~~0014U Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)~~
101034	Single Cell Prenatal Diagnosis, Luna Genetics, Inc.	Prenatal genetics, DNA analysis, single fetal trophoblasts isolated from maternal blood, whole genome amplification, whole genome shotgun Next Generation Sequencing (NGS) of DNA, fetal genome-wide copy number, aneuploidy, deletion, duplication, maternal blood, presence or absence of any genome copy number variations
101035	IMMray PanCan-d	Oncology (pancreas), multiplex biotin/streptavidin immunoassay of 8 proteins (C5, C4,

		Cystatin C, Factor B, OPG, Gelsolin, IGFBP3, CA125) and multiplex electrochemiluminescent immunoassay (ECLIA) of 1 oligosaccharide (CA19-9), serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline.
101041	Versiti Inherited Thrombocytopenia Panel **REVISE - 0276U**	▲0276U Hematology (inherited thrombocytopenia), genomic sequence analysis of 423 genes, blood, buccal swab, or amniotic fluid
101060	miR Sentinel Prostate Cancer Test	Oncology (Prostate) urine exosome-based analysis of 442 small non-coding RNAs (sncRNAs) by RT-QPCR. A statistical classification algorithm reports one of the four results, No Molecular Evidence of Prostate Cancer, or Molecular Evidence of with Low-Risk, Intermediate-Risk or High-Risk Prostate Cancer
101080	RightMed Comprehensive Test	SNP genotyping by real-time PCR - 27 genes reported to provider
101081	OWLiver	Hepatology (liver disease) in-vitro diagnostic (IVD) test that classifies stages of non-alcoholic fatty liver disease (NAFLD). The method consists in the semiquantification of a panel of lipid markers extracted from a patient's serum and measured by high pressure liquid chromatography coupled to high resolution mass spectrometry (UHPLC-HR-MS). The OWLiver Panel combines 28 lipid biomarkers in two algorithms to classify a patient in non-alcoholic steatohepatitis with significant or advance fibrosis (at-risk NASH), non-alcoholic steatohepatitis (NASH), or not NASH (includes Steatosis and healthy patients)
101082	GeneSight Psychotropic	Psychiatry (eg, depression, anxiety, ADHD), genomic analysis panel, variant analysis of 15 genes including deletion/duplication analysis of CYP2D6.
101083	AD-DetectTM Amyloid Beta 42/40 Ratio, Plasma	Beta amyloid, Aβ40 and Aβ42 by LC-MS/MS, ratio, plasma
101084	Visby Medical Sexual Health Click Test	Infectious disease (sexually transmitted infection), pathogen-specific DNA, 3 targets (Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis), amplified probe technique, including multiplex PCR, vaginal swab, each pathogen reported as detected or not detected
101085	RightMed Comprehensive Test Exclude F2 and F5	SNP genotyping by real-time PCR - tests 25 genes
101086	RightMed PGx16 Test	SNP genotyping by real-time PCR - this test provides results on 16 genes
101088	NaviDKD™ Proactive Diagnostic Screening for Kidney Health	Chemical(s) analyzed - protein (Advanced Glycation End Products). A blood (plasma) sample is analyzed for the levels of specific AGEs (Carboxymethyl lysine, methylglyoxal hydroimidazolone and carboxyethyl lysine) using HPLC-MS (High Performance Liquid Chromatography) triple quadrupole mass spectrometry. Those measurements, along

		with current HbA1c and eGFR test results are used in a predictive algorithm to calculate a predictive risk score
101089	RightMed Gene Report	SNP genotyping by real-time PCR - tests 27 genes
101090	MeMed BV®	Infectious disease (bacterial or viral), biochemical assays of three proteins (tumor necrosis factor-related apoptosis-inducing ligand [TRAIL], interferon gamma-induced protein-10 [IP-10], and CRP), utilizing serum, algorithm reported as likelihood of bacterial infection
101091	Xpert Xpress MVP	Infectious disease, bacterial vaginosis and vaginitis, multiplex amplified probe technique for the detection of pathogen-specific DNA, 4 reportable results, bacterial vaginosis associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as a positive or negative result, Includes separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each pathogen reported as detected or not detected.
101092	Xpert CT/NG	Infectious agent detection by nucleic acid (DNA), 2 targets (Chlamydia trachomatis, Neisseria gonorrhoeae), multiplex amplified probe technique, each pathogen reported as detected or not detected; female and male urine, patient-collected vaginal swabs (collected in a clinical setting), clinician-collected endocervical swabs, and female and male pharyngeal and rectal swabs
101093	Pre Tect HPV-Proofer' 7	PreTect HPV-Proofer’7 (Cervical Oncology), qualitative mRNA expression of E6/E7 from HPV 16, 18, 31, 33, 45, 52 and 58 through amplification in real time using qPCR. The mRNA expression specifically report which HPV variant is expressing E6/E7. The assay includes intrinsic sample control and internal control for each of the seven E6/E7 mRNA expression
101095	EUROIMMUN Dermatomycosis	Dermatomycosis or onychomycosis, DNA, 29 genes, microarray, end-point PCR, in situ hybridization, nail, skin, hair, formalin-fixed paraffin embedded, culture, diagnostic algorithm, qualitative report